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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/054,113      | 10/20/2001  | John Vincent Fontana | 8364M               | 6409             |

27752 7590 06/16/2005

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EXAMINER

TRUONG, LINH T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3761

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/054,113

Applicant(s)

FONTANA ET AL.

Examiner

Linh Truong

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "48" has been used to designate both non-securing edge and interior surface of the patch. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim 8 is objected to because of the following informalities: the phrase "the adhesive area comprises surrounding the patch." The Examiner assumes that the word "comprises" is extrafluous and that the word "surrounding" should be changed to "surround" so that the phrase reads as, "the adhesive area surrounds the patch."

***Response to Arguments***

Applicant's arguments with respect to claims 4-12 have been considered but are moot in view of the new ground(s) of rejection.

The Examiner also wants to make the record clear that claim 4 was rejected on page 4 in the non-final rejection mailed out on 10 October 2003.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-12, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder '6,124,522 in view of Conte '5,772,623.

For claims 4, 6, 8, and 11, Schroeder teaches an adhesive applicator comprising;

a) an applicator substrate 6 with a graspable, laterally offset and outwardly extending tab 8 and an adhesive 5a and a cohesive/adhesive area 15 which surrounds the patch,

b) a patch 1 with a first surface and an adhesive 3 on the second surface, c) a release substrate 9 with a graspable, laterally offset and outwardly extending tab 12 that is releasably attached to patch 1 with a release layer 13a that is coated with silicone (figs. 2 and 4) and d) a circumferential lateral edge that has a leading edge proximate to the graspable means of the release substrate and a trailing edge distal to the graspable means of the release substrate (the examiner takes the position that the applicant is not

very specific about the location of the leading and trailing edges in the claim language and, thus, Schroeder's patch meets the applicant's general limitations). Schroeder also teaches varying peel bond strengths. The peel bond strength between the patch and the release substrate (second peel bond) is weaker than the peel bond strength between the applicator-substrate and the patch (first peel bond). (fig. 5 and col. 7, lines 13-26). Schroeder, however does not teach a non-securing edge. Conte teaches a bandage with a non-securing edge 24 (fig. 1A and col. 3, lines 8-11). Patches/bandages with an adhesives on the second surfaces with non-securing edges are well known in the wound dressing art because the non-securing edges eliminates the need for a user to touch the user's skin in order to remove a bandage as taught by Conte (col. 2, lines 5-7). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to substitute the patch of Schroeder with the patch of Conte to provide removal of the bandage without further injuring or irritating the wound.

Per claim 5, the first peel bond is weaker than the bond between the patch and the target surface because when the adhesive applicator is being applied, the user first separates the applicator substrate 6 and patch 1 from the release substrate 9, then secondly applies patch 1 onto the target by using applicator substrate 6, and then finally removes the applicator substrate 6 from patch 1, leaving only the patch on the target surface (fig. 5 and col. 7, lines 13-26).

For claim 7, Schroeder does not teach a sinusoidal pattern for the leading or trail edge contact areas but does state that "articles of nearly any size or shape may be packaged" (col. 4, lines 47-50). At the time the invention was made, it would have been

an obvious matter of design choice to a person of ordinary skill in the art to have a sinusoidal pattern for the leading or trail edge contact areas, because Applicant has not disclosed that provide an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the rectangular (with curvilinear edges) shape of Schroeder's.

For claims 9-10, Schroeder teaches a patch treated with nicotine (col. 4, lines 37-40).

For claims 18-21, Schroeder discloses the claimed invention except for the ranges of percentages of the circumferential edge for the leading and trailing edges *and* the leading and trailing contact areas. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the leading edge to be 10% to 30% of the circumferential edge and the trailing edge to be 10% to 35% of the circumferential edge and the leading edge contact area to be from about 0.4 cm<sup>2</sup> to 2 cm<sup>2</sup> and the trailing edge contact area to be from about 0.4 cm<sup>2</sup> to about 2 cm<sup>2</sup>, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder '6,124,522 in view of Conte '5,772,623 and in view of applicant's own admission.

For claim 13, Schroeder does not specifically teach that the applicator substrate comprises polyester film.

For claim, 14, Schroeder does not specifically teach that the patch comprises polyethylene film.

For claim 15, Schroeder does not specifically teach that the release substrate comprises siliconized polyester.

For claims 13-15, applicant admitted that "Suitable materials for use as the applicator substrate, patch, and release substrate are intended in their broadest sense," and then lists various examples and references the book by Joseph Hanlon, *Handbook of Package Engineering* for the production methods and use of different materials for the applicator substrate, patch, and release substrate [0036]. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Schroeder with an applicator substrate comprised of a polyester film, a patch comprised of polyethylene film, and a release substrate comprised of siliconized polyester, respectively, for alternate materials for the different parts of a dressing.

Claims 16,17, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroeder '6,124,522 in view of Conte '5,772,623 and in further view of Sessions et al. '6,043,406.

For claims 16,17, and 23, Schroeder teaches that the patch can contain nicotine or a biochemical (col. 4, lines 37-40) but does not teach that the patch comprises hormones, and thus, does not teach a method for delivering hormones. Hormones are

among various medications added to wound dressings and are well known in the art as taught by Sessions et al. (col.4, line 66-col. 5, line 16). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the patch of Schroeder with the hormones of Sessions et al. for the delivery of hormones into patients for promoting tissue growth in patients.

### ***Conclusion***

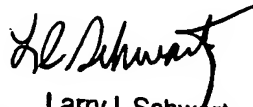
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 571-272-4938. The examiner can normally be reached on Mondays through Fridays from 10:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached at 571-272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

*L.T.*

  
Larry I. Schwartz  
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